Section E – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR § 807.92.

Name:	Jennifer Ng Regulatory Affairs
Address:	Excel Tech, Ltd. 2568 Bristol Circle Oakville, Ontario Canada, L6H 5S1
Telephone:	(905) 829-5300 x244
Fax:	(905) 829-5304
E-mail:	jng@xltek.com
Common Names:	96 Channel EEG Headbox
Classification Name:	Electroencephalograph
Description:	The 96 Channel EEG Headbox is a digital electroencephalograph that can also record pulse oximetry signals.
Intended Use:	The 96 Channel EEG Headbox is intended to be used as an electroencephalograph: to acquire, store, and archive electroencephalographic signals with additional capabilities to record other physiological signals such as pulse oximetry.
Predicate Devices:	Excel tech, Ltd. Neuro Works 128 Channel EEG 510(k)# K000919 Masimo SET Radical Pulse Oximeter 510(k)# K992340
Substantial Equivalence:	The XLTEK 96 Channel EEG Headbox is substantially equivalent in safety and effectiveness to the Excel Tech, Ltd. NeuroWorks 128 Channel EEG and the Masimo SET Radical Pulse Oximeter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

Mr. John Mumford
President
Excel Tech, Ltd.
2568 Bristol Circle
Oakville, Ontario
Canada, L6H 5S1

Re: K021599
Trade/Device Name: 96 Channel EEG Headbox, Model EMU96
Regulation Numbers: 882.1400, 882.1420, and 870.2700
Regulation Names: Electroencephalograph, Electroencephalogram (EEG) Signal Spectrum Analyzer, and Oximeter
Regulatory Class: II
Product Codes: GWQ, GWS and DQA
Dated: April 29, 2002
Received: May 15, 2002

Dear Mr. Mumford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

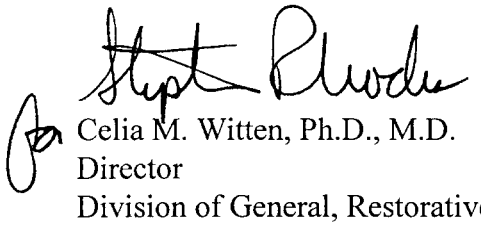
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section D – Statement of Indications for Use

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510(k) Number (if known): K021599

Device Name: 96 Channel EEG Headbox

Indications for Use: The 96 Channel EEG Headbox is intended to be used as an electroencephalograph: to acquire, store, and archive electroencephalographic signals with additional capabilities to record other physiological signals such as pulse oximetry.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____

(Per 21§ CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021599